IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD. and BARR LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Mallinckrodt LLC ("Mallinckrodt"), for their Complaint against Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Barr Laboratories Inc. (collectively "Teva" or "Defendants"), allege as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo is a specialty pharmaceuticals company engaged in the research, development, sale and marketing of prescription pharmaceuticals used, among other things, to treat and manage pain. Endo markets and distributes OPANA® ER, an innovative opioid painkiller designed to be crush-resistant (alternatively referred to herein as "Opana ER CRF").

2. Plaintiff Mallinckrodt is a Delaware company, having its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri 63042. Mallinckrodt manufactures and distributes products used in diagnostic procedures and in the treatment of pain and related conditions.

3. Upon information and belief, defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a company organized and existing under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tikva, Israel.

4. Upon information and belief, Teva Ltd. is a pharmaceutical company engaged in the world-wide development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

5. Upon information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, is a wholly owned subsidiary of Teva Ltd., and maintains its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

6. Upon information and belief, Teva USA is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, defendant Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of the State of Delaware, is an indirect wholly owned subsidiary of Teva USA, and maintains its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey.

8. Upon information and belief, Barr is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

NATURE OF ACTION

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

11. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

12. Teva USA and Barr are Delaware corporations and, therefore, are subject to personal jurisdiction in Delaware.

13. Upon information and belief, Teva Ltd. conducts its North American operations in part through Teva USA and Barr. Together, Teva Ltd., Teva USA, and Barr collaborate in the research, development, manufacture, testing, distribution and/or the sale of a number of pharmaceutical products manufactured and sold pursuant to approved abbreviated new drug applications within the United States, the State of Delaware, and this judicial district.

14. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they have committed—or aided, abetted, planned, contributed to, or participated in the commission of—tortious conduct in the State of Delaware that has led to foreseeable harm and injury to Endo and Mallinckrodt.

15. Upon information and belief, Teva USA has submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) ("ANDA No. 20-4324" or "Teva's ANDA"), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets, ("Teva's ANDA Products"), as a generic version of the drug described in Endo's Supplemental New Drug Application ("sNDA") 201655.

16. Upon information and belief, Defendants intend to manufacture generic Opana ER CRF for distribution and sale in this judicial district should Teva's ANDA be approved by FDA.

17. Moreover, Defendants maintain continuous and systematic contacts with the State of Delaware and this District.

18. Upon information and belief, Defendants currently sell significant quantities of generic drug products in the District of Delaware. Those products include, for example, generic versions of Ambien®, Prozac®, and Zocor®. A list of generic products manufactured and sold by Teva in the United States is provided by Teva at http://www.tevagenerics.com.

19. Furthermore, Teva has been sued as a patent infringer in this Court, and has declined to contest that this Court has personal jurisdiction over it. *See, e.g., Acorda Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, 14-cv-941-LPS; *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 14-cv-874-SLR.

20. Based on the facts and causes alleged herein, and for additional reasons to be developed through discovery, this Court has personal jurisdiction over Defendants.

FACTUAL BACKGROUND

The Drug Approval Process

21. A company seeking to market a new drug in the United States must first obtain approval from FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a).

22. On the other hand, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding

of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

Endo's Opana ER CRF NDA

23. On December 12, 2011, FDA approved Endo's sNDA 201655 under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for a new dosage form of Opana ER, which is a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain (hereinafter, "Opana ER CRF").

24. Opana ER CRF is distributed and sold throughout the United States for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

THE '737 PATENT

25. On August 19, 2014, the PTO duly and legally issued U.S. Patent No. 8,808,737 ("the '737 Patent"), entitled "Method of Treating Pain Utilizing Controlled Release Oxymorphone Pharmaceutical Compositions and Instruction on Dosing for Renal Impairment" to Endo Pharmaceuticals Inc. as assignee. Harry Ahdieh is named as the inventor. A true and correct copy of the '737 Patent is attached as Exhibit A.

26. Endo is the sole owner and assignee of the '737 Patent.

27. Opana ER CRF is covered by one or more claims of the '737 Patent.

28. Endo has submitted patent information regarding the '737 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '737 Patent in the Orange Book for Opana ER CRF.

THE ’779 PATENT

29. On October 28, 2014, the PTO duly and legally issued U.S. Patent No. 8,871,779 (“the ’779 Patent”), entitled “Process for Preparing Morphinan-6-One Products with Low Levels of α,β-Unsaturated Ketone Compounds” to Mallinckrodt as assignee. Henry J. Buehler, William E. Dummitt, Anthony Mannino, Dennis C. Aubuchon, and Hong Gu are named as inventors. A true and correct copy of the ’779 Patent is attached as Exhibit B.

30. Mallinckrodt is the assignee and owner of the ’779 Patent.

31. Endo has an exclusive license to the ’779 Patent from Mallinckrodt in the appropriate field of use, including the exclusive right to enforce the ’779 Patent in that field.

32. Opana ER CRF is covered by one or more claims of the ’779 Patent.

33. Endo has submitted patent information regarding the ’779 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the ’779 Patent in the Orange Book for Opana ER CRF.

TEVA’S ANDA FILING

34. Upon information and belief, some time before September 20, 2012, Teva submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application (ANDA No. 20-4324) under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets (“Teva’s ANDA Products”), as a generic version of the products described in sNDA 201655.

35. Pursuant to its ANDA, Teva is seeking FDA approval to make, use, and sell its ANDA Products prior to expiration of the ’737 and ’779 Patents.

ENDO'S COUNT I: INFRINGEMENT OF THE '737 PATENT

36. Endo incorporates each of paragraphs 1-35 above as if set forth fully herein.

37. The submission of Teva's ANDA No. 20-4324 to FDA constitutes infringement of the '737 Patent under 35 U.S.C. § 271(e)(2)(A).

38. Teva is seeking FDA approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Products before expiration of the '737 Patent. On information and belief, if granted approval, Teva intends to launch its ANDA Products before expiration of the '737 Patent.

39. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

40. Any such launch by Teva of its ANDA Products before expiration of the '737 Patent would cause Endo to suffer immediate and irreparable harm.

ENDO'S COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '737 PATENT

41. Endo incorporates each of paragraphs 1-40 above as if set forth fully herein.

42. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

43. There is an actual case or controversy such that the Court may entertain Endo's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

44. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Teva's ANDA Products before expiration of the '737 Patent.

45. Defendants' actions indicate their intention to manufacture, offer to sell, and sell Teva's ANDA Products before expiration of the '737 Patent, and further indicate a refusal to change the course of its action in the face of acts by Endo.

46. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

47. Endo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products by Defendants before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT III:
INFRINGEMENT OF THE '779 PATENT

48. Endo and Mallinckrodt incorporate each of paragraphs 1-35 above as if set forth fully herein.

49. The submission of Teva's ANDA No. 20-4324 to FDA constitutes infringement of the '779 Patent under 35 U.S.C. § 271(e)(2)(A).

50. Teva is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before expiration of the '779 Patent. On information and belief, if

granted approval, Teva intends to launch Teva's ANDA Products before expiration of the '779 Patent.

51. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

52. Any launch by Teva of its ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

53. Upon information and belief, Defendants are aware of the existence of the '779 Patent, and are aware that the commercial manufacture, sale, and offer for sale of Teva's ANDA Products constitutes infringement of the '779 Patent.

ENDO AND MALLINCKRODT'S COUNT IV:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '779 PATENT

54. Endo and Mallinckrodt incorporate each of paragraphs 1-35 and 48-53 above as if set forth fully herein.

55. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

57. Teva has made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Teva's ANDA Products before expiration of the '779 Patent.

58. Defendants' actions indicate its intention to manufacture, offer to sell, sell and/or import the products that are the subject of Teva's ANDA before expiration of the '779 Patent.

59. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

60. Any launch by Teva of its ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

61. Plaintiffs are entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products by Defendants before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo and Mallinckrodt respectfully request the following relief:

A. A judgment that Teva has infringed the '737 Patent, and a declaration that Teva's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '737 Patent;

B. A declaration that the '737 Patent is valid and enforceable;

C. A judgment that Teva has infringed the '779 Patent, and a declaration that Teva's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '779 Patent;

D. A declaration that the '779 Patent is valid and enforceable;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Teva's ANDA No. 20-4324 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the '737 and '779 Patents, including any extensions;

F. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Teva, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '737 and '779 Patents for the full terms thereof, including any extensions;

G. An order that damages or other monetary relief be awarded to Plaintiffs if Teva engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Teva's ANDA Products, or in inducing such conduct by others, prior to the expiration of the '737 and '779 Patents, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

H. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Endo in this action; and

I. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney

Jack B. Blumenfeld (#1014)
Julia Heaney (#3052)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jheaney@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Jonathan D. Loeb
DECHERT LLP
2440 W. El Camino Real
Suite 700
Mountain View, CA 94040
(650) 813-4800

Martin J. Black
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000

Robert D. Rhoad
DECHERT LLP
902 Carnegie Center
Suite 500
Princeton, NJ 08540
(609) 955-3200

Attorneys for Endo Pharmaceuticals Inc.

Jeffrey J. Toney
KASOWITZ BENSON TORRES & FRIEDMAN LLP
333 Twin Dolphin Drive
Suite 200
Redwood Shores, CA 94065
(650) 453-5170

Attorneys for Mallinckrodt LLC

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